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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,508	11/30/2006	Anthony John Freemont	69494-4	6795

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EXAMINER	
SGAGIAS, MAGDALENE K	

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,508	FREEMONT ET AL.	
	Examiner	Art Unit	
	MAGDALENE K. SGAGIAS	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-37 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3-14, 36-37, drawn to an isolated mesenchymal stromal stem cell (MSSC) that has been differentiated in vitro towards, or to, an intervertebral disc (IVD) cell phenotype.

Group II, claim(s) 2, 15-20, 35-37, drawn to an isolated mesenchymal stromal stem cell (MSSC) characterized in that it is: a) differentiated in vitro towards, or to, a intervertebral disc (IVD) cell phenotype; and b) genetically transformed with an exogenous gene which codes for a protein that
reduces degeneration of an intervertebral disc.

Group III, claim(s) 21, drawn to a method of treating spinal conditions characterized by degeneration of the intervertebral disc comprising: providing a composition comprising administering to a diseased intervertebral disc of a subject in need of such treatment an isolated MSSC that has been differentiated in vitro towards, or to, an IVD cell phenotype and administering said composition to a diseased intervertebral disc of a subject in need of such treatment.

Group IV, claim(s) 22, drawn to a method of treating spinal conditions characterized by degeneration of the intervertebral disc comprising: providing a composition comprising administering to a diseased intervertebral an isolated MSSC, wherein said MSSC has been: (a) differentiated in vitro towards, or to, a IVD cell phenotype, and (b) genetically transformed with an exogenous gene which codes for a protein that reduces degeneration of an intervertebral disc and administering said composition to a diseased intervertebral disc of a subject in need of such treatment.

Group V, claim(s) 23, drawn to a method for causing mesenchymal stromal stem cells to differentiate towards IVD cells comprising exposing cultured mesenchymal stromal stem cells to increasing pressures of up to 30 psi (2.1MPa).

Group VI, claim(s) 24, drawn to a method for causing mesenchymal stromal stem cells to differentiate

towards IVD cells comprising co-culturing NP cells and mesenchymal stromal stem cells (MSSCs) together.

Group VII, claim(s) 25, drawn to a method for causing mesenchymal stromal stem cells to differentiate towards IVD cells comprising culturing mesenchymal stromal stem cells in media that has previously been exposed exoposed to NP cells.

Group VIII, claim(s) 26, drawn to a method for causing mesenchymal stromal stem cells to differentiate towards IVD cells comprising culturing mesenchymal stromal stem cells in an atmosphere in which oxygen pressure is reduced to less than 5%.

Group IX, claim(s) 27-28, drawn to a method for causing mesenchymal stromal stem cells (MSSCs) to differentiate towards IVD cells comprising encapsulating MSSCs in a gel and growing
the encapsulated cells in a medium for up to 5 weeks during which time a cyclical load equivalent to that experienced in vivo is exerted using hydraulic.

Group X, claim(s) 27-28, drawn to a method for causing mesenchymal stromal stem cells (MSSCs) to differentiate towards IVD cells comprising encapsulating MSSCs in a gel and growing
the encapsulated cells in a medium for up to 5 weeks during which time a cyclical load equivalent to that experienced in vivo is exerted using other methodology than hydraulic.

Group XI, claim(s) 27, 29, drawn to a method for causing mesenchymal stromal stem cells (MSSCs) to differentiate towards IVD cells comprising encapsulating MSSCs in a gel and growing
the encapsulated cells in a medium for up to 5 weeks during which time a cyclical load equivalent to that experienced in vivo is exerted using hydraulic, wherein the media is a conditioned medium in which IVD cells have previously been grown.

Group XII, claim(s) 27, 29, drawn to a method for causing mesenchymal stromal stem cells (MSSCs) to differentiate towards IVD cells comprising encapsulating MSSCs in a gel and growing the encapsulated cells in a medium for up to 5 weeks during which time a cyclical load equivalent to that experienced in vivo is exerted using other methodology than hydraulic, wherein the media is a conditioned medium in which IVD cells have previously been grown.

Group XIII, claim(s) 27, 30, drawn to drawn to a method for causing mesenchymal stromal stem cells (MSSCs) to differentiate towards IVD cells comprising encapsulating MSSCs in a gel and growing the encapsulated cells in a medium for up to 5 weeks during which time a cyclical load equivalent to that experienced in vivo is exerted using hydraulic, wherein the MSSCs are co-cultured with Nucleus Pulposus cells/IVD cell, wherein the MSSCs are co- cultured with Nucleus Pulposus cells/IVD cell.

Group XIV, claim(s) 27, 30, drawn to a method for causing mesenchymal stromal stem cells (MSSCs) to differentiate towards IVD cells comprising encapsulating MSSCs in a gel and growing the encapsulated cells in a medium for up to 5 weeks during which time a cyclical load equivalent to that experienced in vivo is exerted using other methodology than hydraulic, wherein the MSSCs are co- cultured with Nucleus Pulposus cells/IVD cell.

Group XV, claim(s) 27, 31-34, drawn to drawn to a method for causing mesenchymal stromal stem cells (MSSCs) to differentiate towards IVD cells comprising encapsulating MSSCs in a gel and growing the encapsulated cells in a medium for up to 5 weeks during which time a cyclical load equivalent to that experienced in vivo is exerted using hydraulic, wherein the oxygen pressure is reduced to less than 5% of the atmosphere in which the cells are cultured.

Group XVI, claim(s) 27, 31-34, drawn to drawn to a method for causing mesenchymal stromal stem cells (MSSCs) to differentiate towards IVD cells comprising encapsulating MSSCs in a gel and growing the encapsulated cells in a medium for up to 5 weeks during which time a cyclical load equivalent to that experienced in vivo is exerted using other methodology than hydraulic, wherein the oxygen pressure is reduced to less than 5% of the atmosphere in which the cells are cultured.

The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Winter et al, [Engineer, 9: 825 (2003) ETES, Abstract #141 (IDS)] disclose the isolation of adult mesenchymal stem cells provide a source for autologous intervertebral-disc like cells (abstract). The Winter reference renders claim 1, among the others not novel. Thus, the technical feature of an isolated mesenchymal stromal stem cell (MSSC) that has been differentiated in vitro towards, or to, an intervertebral disc (IVD) cell phenotype is not special and the groups are not so linked under PCT Rule 13.1. Additionally, the claimed methods in group III-XVI have distinct method steps, produce different products and/or different results, which are not coextensive and which do not share the same technical feature.

Upon election of any one of group I-XVI, Applicant is required to make the following additional election, even though this is not a species election it is a restriction requirement:

1. Upon election of one group, Applicant is required to elect only blood or only bone marrow or only adipose tissue of claim 6 as each one of them is associated with patentably distinct modes of action, biological characteristics and structural manifestations.

2. Upon election of one group, Applicant is required to elect only step of claim 8 as each one of them is associated with patentably distinct modes of action, biological characteristics and structural manifestations.

3. Upon election of one group, Applicant is required to elect only scaffolds or only gels of claim 20 as each one of them is associated with patentably distinct modes of action, biological characteristics and structural manifestations.

4. Upon election of one group, Applicant is required to elect only TGFI3, or only CDMP 1 or only CDMP2 of claim 28 as each one of them is associated with patentably distinct modes of action, biological characteristics and structural manifestations.

5. This application contains claim 15 directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1) genes encoding proteins involved in the regulation of inflammation:

2) genes encoding cytokines,

3) genes encoding inhibitors of cytokines,: and

4) genes encoding inhibitors of degradative enzymes

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: for example genes encoding for proteins involved in the regulation of inflammation are patentable distinct from genes encoding cytokines because they are structurally distinct and have different function and characteristics.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

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/Anne-Marie Falk/
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